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CONTRACT MANAGEMENT

DOD's Anthrax Vaccine Manufacturer Will Continue to Need Financial Assistance

Statement of David E. Cooper, Associate Director
Defense Acquisition Issues
National Security and International Affairs Division

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Mr. Chairman and Members of the Committee and Subcommittee:

It is a pleasure to be here today to discuss the contractual relationship between the Department of Defense (DOD) and BioPort Corporation for the production of anthrax vaccine. DOD regards the use of anthrax by an enemy as the single greatest biological threat to U.S. military forces. BioPort, the only company licensed by the Food and Drug Administration (FDA) to produce the anthrax vaccine in the United States, has experienced financial difficulties that have jeopardized DOD's anthrax vaccination program. In response to the company's problems, DOD has provided BioPort financial assistance. I will discuss (1) the "extraordinary contractual relief" DOD provided BioPort in 1999 and (2) additional financial assistance DOD is providing BioPort in 2000.[1]

We have issued a number of products on DOD's anthrax vaccination program and the larger issue of biological terrorism. A list of these products is at attached to this statement.

Summary

Last year, DOD provided BioPort extraordinary contractual relief so that the company would have sufficient operating capital to preclude disrupting, and possibly ending, the anthrax vaccine program. Among other things, DOD substantially increased the original contract price and provided an interest-free advance payment to BioPort of $18.7 million. In providing the relief, DOD assumed FDA would approve the company's vaccine production processes in its renovated facilities by the end of 1999. However, in November 1999, FDA reviewed the company's manufacturing processes and identified numerous deficiencies. According to DOD officials, BioPort is now not expected to obtain FDA's approval until the end of this year. The delay in obtaining FDA approval has caused BioPort to experience continuing financial problems.

Recognizing the company's current financial difficulties, DOD has taken a number of additional actions to help improve BioPort's financial situation. In February 2000, DOD modified BioPort's contract to provide an additional $13 million to, in part hire technical assistance in obtaining FDA approval of BioPort's production processes. DOD also extended the schedule for BioPort to repay its interest-free advance and returned $7.4 million that the company had repaid for the $18.7 million in advance it had received from DOD.

[1] The provision of "extraordinary contractual relief" was provided under Public Law 85-804.

In March 2000, DOD notified BioPort that it wants BioPort to stop anthrax vaccine production for now. This action reduces DOD's risk of paying for vaccine that the FDA may ultimately not approve and also allows BioPort to focus on obtaining FDA approval. However, the company's financial condition is worsened because BioPort will no longer receive revenues from producing the vaccine. To mitigate the consequences of its action, DOD intends to provide additional financial assistance to BioPort to sustain the production line.

Background

From the 1970s until 1998, DOD procured anthrax vaccine from a facility owned by the state of Michigan. The facility, first known as the Biologic Products Division of the Michigan Department of Public Health and later as the Michigan Biologic Products Institute, was the only facility in the country licensed by the FDA to produce the vaccine. In 1997, FDA identified numerous manufacturing problems that threatened revocation of the facility's license. In response to concerns about the potential loss of anthrax vaccine production, DOD began funding renovation efforts. Production was shut down in early 1998. Later, in the summer of 1998, Michigan sold the facility to the BioPort Corporation for $25 million. The company paid $3.25 million in cash, $12.15 million secured in notes payable to Michigan, and agreed to pay $9.6 million based on other obligations, including a percentage of future sales. The contracts DOD had with the Michigan facility were transferred to BioPort.

In June 1999, we testified that over the previous 11 years, DOD had provided about $112 million in contracts, including options, to procure the anthrax vaccine and help ensure the viability of the facility.[2] After, BioPort took over the facility, it experienced delays in completing renovation efforts, and production of the vaccine was 5 months behind schedule when it resumed production in May 1999. As a result of these delays, the company did not receive the revenues it expected and faced a serious cash flow problem, which raised significant doubt as to whether BioPort could to meet contract obligations. We attributed the company's cash flow problem to its failure to achieve an overly optimistic business plan. The company's business plan, in addition to meeting DOD's requirements, provided for the sale of anthrax vaccine to other customers. At that time, BioPort proposed several actions to resolve its financial problems, including asking DOD for advance payments and increasing contract prices.

[2] *Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer* (GAO/T-NSIAD-99-214, June 30, 1999).

expenses. As a result, DOD has taken a number of actions in the short term to keep the company operating and help deal with issues that must be resolved before the company can obtain FDA approval. In February 2000, DOD modified its contract with BioPort to provide, at least, an additional $13 million to (1) hire consultants to assist in obtaining FDA's approval of BioPort production processes and (2) obtain subcontractor support to test the anthrax vaccine. Additional funds, yet to be determined, will be provided to BioPort for it to establish a redundant capability to package, fill, and store the vaccine.

In February 2000, DOD also agreed to return about $7.4 million of the advance payment that the company had repaid under the terms of the extraordinary contractual relief provided in 1999. While this action did not increase the cost of the contract, it did extend the schedule under which BioPort is to repay the $18.7 million advance payment. In exchange for the extension, BioPort agreed to stop producing its plasma products and suspend production of the rabies vaccine so that the company could focus its attention on obtaining FDA approval.

In March 2000, DOD notified BioPort that it intends to stop the company's anthrax production operations for now. FDA indicated that current production operations might result in potentially unusable vaccine because it has yet to approve the manufacturing process. This production stoppage reduces DOD's risk of paying for vaccine that the FDA may ultimately not approve and allows BioPort to focus on obtaining FDA approval. However, since payment under the contract is largely based on vaccine production rather than on FDA approval for release, the stop in production will worsen BioPort's financial condition. To mitigate the consequences of stopping production, DOD intends to provide additional financial assistance to BioPort to sustain its production line. The amount of additional assistance has not been determined.

Mr. Chairman, Members of the Committee and Subcommittee, that concludes my prepared remarks. We would be happy to answer any questions you have at this time.

Contact and Acknowledgment

For future questions regarding this testimony, please contact David E. Cooper at (202) 512 –4125. Individuals making key contributions to this testimony were Johana R. Ayers, Ralph Dawn, and Paul M. Greeley.

Attachment

Related GAO Products

Medical Readiness: DOD Continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/T-NSIAD-00-157, Apr. 13, 2000).

Combating Terrorism: Chemical and Biological Supplies Are Poorly Managed (GAO/T-HEHS-AIMD-00-59, Mar. 8, 2000).

Combating Terrorism: Chemical and Biological Supplies Are Poorly Managed (GAO/HEHS/AIMD-00-36, Oct. 29, 1999).

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, Oct. 22, 1999).

Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Combating Terrorism: Observations on Growth in Federal Programs (GAO/T-NSIAD-99-181, June 9, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives (GAO/T-NSIAD-99-112, Mar. 16, 1999).

Combating Terrorism: Observations on Federal Spending to Combat Terrorism (GAO/T-NSIAD/GGD-99-107, Mar. 11, 1999).

Combating Terrorism: Efforts to Protect U.S. Forces in Turkey and the Middle East (GAO/T-NSIAD-98-44, Oct. 28, 1997).

Combating Terrorism: Status of DOD Efforts to Protect Its Forces Overseas (GAO/NSIAD-97-207, July 21, 1997).

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